

Amendments to the Drawings

FIG. 5 has been amended to replace reference character "96" with "34."

Attachment: Replacement Sheet
Annotated Marked-Up Drawings

REMARKS

The remainder of this Amendment is set forth under appropriate subheadings for the convenience of the Examiner.

Amendments to the Specification

The specification has been amended to replace reference character "96" on page 20, lines 25 and 27, and page 21, lines 17 and 21 with "34," as suggested by the Examiner. Designation of a porous support with reference character "34" can be found in FIG. 1, as originally filed. No new matter has been added.

Amendments to the Claims

Claim 1 has been amended to define the claimed invention more clearly. Support for the newly-recited feature "whereby deactivated components of the nucleic acid amplification inhibitor component are retained by the porous support or are soluble fragments that do not interfere with nucleic acid amplification procedures" can be found in the specification, for example, on page 7, lines 22-24. Support for "a magnetic substrate that separates the sample to be contacted with the porous support from at least a portion of a raw sample and deposits the sample at the porous sample" can be found in the specification, for example, on page 10, line 27 through page 11, line 5, on page 11, lines 23-25, and on page 13, lines 1-17.

Claim 2 has been amended to recite that the magnetic substrate of Claim 1 is included in separating means that further includes the recited components. Support for this amendment can be found in original Claims 1 and 2.

New Claim 22 has been added to recite that the deactivating agent of Claim 1 is a chaotropic salt. Support for this new claim can be found in the specification, for example, on page 8, lines 3 and page 13, lines 28-29.

New Claim 23 has been added to recite that the magnetic substrate is located between the opening and the porous support. Support for this new claim can be found in the drawings, as originally filed, for example, in FIGs. 9-11.

New Claim 24 has been added to defined the claimed invention more clearly by reciting that "directing of fluid through the porous support also separates at least a portion of a nucleic acid component of the sample from the nucleic acid amplification inhibitor component retained by the porous support." Support for this new claim can be found in the specification, for example, on page 9, lines 9-14.

No new matter has been added.

Amendments to the Abstract

The abstract of the present specification has been amended to replace the term "means that include a magnetic substrate" with "by a magnetic substrate" to describe Applicant's invention more clearly and to be consistent with currently-amended independent Claim 1.

No new matter has been added.

Objection to Drawings

FIG. 5 is objected to, because reference characters "34" and "96" have both been used to designate a porous support.

As discussed above, FIG. 5 has been amended to replace "96" with "34." Also, the specification has been amended accordingly to accommodate the amendment to FIG. 5. As such, Applicants respectfully request withdrawal of this objection.

Claim Rejection under 35 U.S.C. § 102(e)

Claims 1-9 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. 6,440,725 to Pourahmadi, *et al.* (hereinafter "Pourahmadi, *et al.*") In particular, the Examiner referenced column 6, lines 1-4, column 12, lines 30-31 and lines 34-50, and column 18, lines 40-50 of Pourahmadi, *et al.* in support of this rejection of Applicants' claimed invention.

Pourahmadi, *et al.* disclose cartridge **101** for separating a desired analyte from a fluid sample. The cartridge includes sample port **103**, mixing chamber **107** for mixing of the sample with a lysing reagent from storage chamber **109**, lysing chamber **119**, and

flow-through component **122**. As described on column 9, lines 8-64 and column 16, line 12 through column 17, line 24, in cartridge **10** of Pourahmadi, *et al.*: i) a fluid sample is lysed as a lysing reagent of chamber **109** contacts the fluid sample; ii) the fluid sample and a lysing reagent continue to flow into the lysing chamber **119** where the sample contacts a filter, and lysed cells, spores, microorganisms, cell debris and other insoluble materials are captured; iii) the crude extract that includes soluble portion of the sample then travels down to flow-through component **122** where nucleic acid in the crude extract binds to component **122** while other undesirable soluble denatured proteins, cell membrane particles and salts are washed away by a washing reagent (see column 17, lines 8-14); and iv) the nucleic acid bound to component **122** is then eluted by an elution fluid from storage region **127**. Pourahmadi, *et al.* also discusses the use of a reservoir of magnetic beads. The beads can be functionalized with various binding agents, and manipulated within the cartridge by externally applied magnetic fields to mix fluids or manipulate flow within the cartridge.

Applicants' claimed invention includes a porous support that includes a deactivating agent, and a magnetic substrate. The magnetic substrate *separates a sample* that includes a nucleic acid component *from a raw sample* and then *deposits the sample at a porous support that includes a deactivating agent*. The deactivating agent deactivates nucleic acid amplification inhibitors for further purification of the sample. More specifically, directing a fluid through the porous support separates at least a portion of a nucleic acid component of the sample from the porous support, whereby deactivated components of nucleic acid amplification inhibitor component are retained by the porous support or are soluble fragments that do not interfere with nucleic acid amplification procedures.

Unlike Applicants' claimed invention, there is *no* disclosure or suggestion in Pourahmadi, *et al.* of an apparatus that includes a magnetic substrate that *separates a sample from a raw sample*, and *deposits the sample at a porous support* that includes a deactivating agent. Also unlike Applicants' claimed invention, there is *no* disclosure or suggestion in Pourahmadi, *et al.* of *a porous support that includes a deactivating agent*, whereby directing a fluid through the porous support separates at least a portion of a

nucleic acid component and whereby deactivated components of a nucleic acid amplification inhibitor component are retained by the porous support or are soluble fragments that do not interfere with nucleic acid amplification procedures. In contrast to the Examiner's assertion, column 12, lines 34-50 of Pourahmadi, *et al.* does **not** teach a porous support that includes a deactivating agent that deactivates nucleic acid amplification inhibitors, such as a chaotropic salt. More specifically, dried agents listed by Pourahmadi, *et al.* at column 12, lines 21-50 and set forth below do **not** include a deactivating agent that deactivates nucleic acid amplification inhibitors:

Dried reagents can be employed as precursor materials for reconstitution and solution-phase interaction or as solid-phase reagents, including pH indicators; redox indicators; enzymes such as horseradish peroxidase, alkaline phosphatase, reverse transcriptase, DNA polymerase, and restriction enzymes; enzyme substrates; enzyme-antibody or enzyme-antigen conjugates; DNA primers and probes; buffer salts; and detergents. Furthermore, solid-phase reagent coatings such as serum albumin, streptavidin, and a variety of cross-linkable proteins such as polysaccharides may be employed at the interactive region.

Therefore, the subject matter of independent Claim 1 is novel and non-obvious in view of Pourahmadi, *et al.* Claims 2-9 depend from Claim 1, and, thus, these claims are also novel and non-obvious in view of Pourahmadi, *et al.* at least for the reasons set forth above. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Claim Rejection under 35 U.S.C. § 102(a)/102(e)

Claim 1 is rejected under 35 U.S.C. § 102(a)/102(e) as being anticipated by U.S. 6,374,684 to Dority (hereinafter "Dority"). In particular, the Examiner referenced column 1, line 64 - column 2, line 4, and column 2, line 3 of Dority in support of this rejection of Applicants' claimed invention.

As described above, Applicants' claimed apparatus comprises a magnetic substrate that *separates a sample from a raw sample*, and *deposits the sample at a porous support* for subsequent deactivation of the nucleic acid amplification inhibitors included in the sample. The *porous support includes a deactivating agent* that deactivates a nucleic acid amplification inhibitor component of a sample contacting the porous support.

Dority discloses a fluid control and processing system for controlling fluid flow among a plurality of chambers. The system comprises a body including a fluid sample processing region continuously coupled with a fluid displacement chamber.

Dority does not disclose or suggest Applicant's claimed apparatus as set forth in Claim 1. Although Dority discloses the use of a magnetic separation matrix as a possible active member of its fluid sample processing region among a variety types of examples of active members, *nowhere* does Dority teach the use of a magnetic substrate that separates a sample from a raw sample, and deposits the sample at a porous support including a deactivating agent that deactivates a nucleic acid amplification inhibitor for further purification. Also, although Dority discloses the use of filter 27 as an active member of its fluid sample processing region to facilitate processing of the fluid (see column 3, lines 54-65), *nowhere* does Dority teach the use of a porous support including a deactivating agent that deactivates a nucleic acid amplification inhibitor.

Thus, the subject matter of Claim 1 is novel and non-obvious in view of Dority. Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

SUMMARY AND CONCLUSIONS

As discussed above, currently-amended Claims 1-9 are novel and non-obvious in view of Pourahmadi, *et al.* and Dority. Therefore, in view of the above amendments and remarks, it is believed that all pending claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a

telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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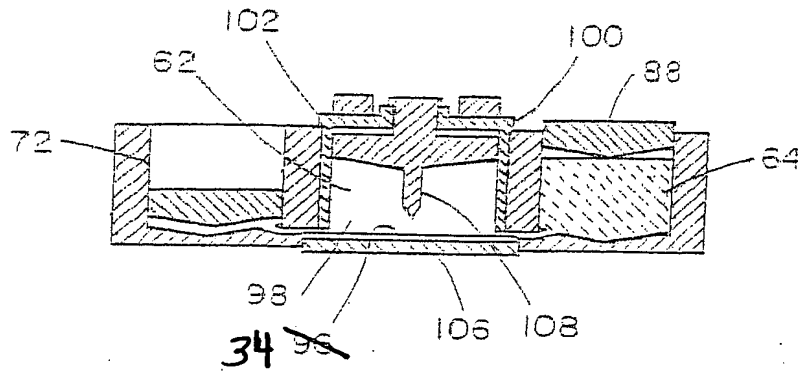


FIG. 5

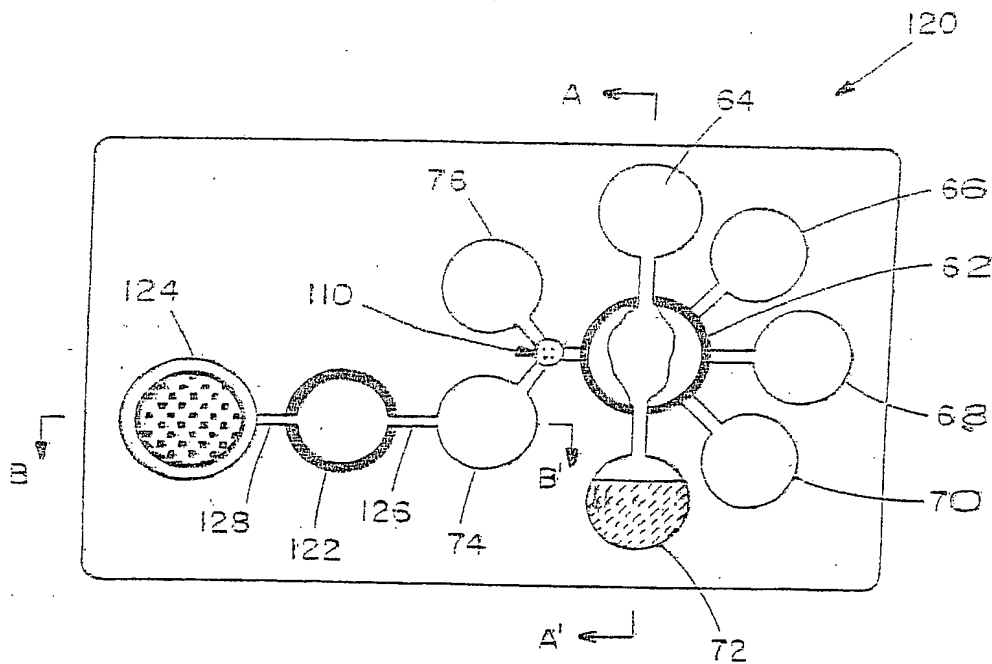


FIG. 6